DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

0048 5 MAR 29 P2:06
MAR 24 2005

Jerry S. Roth, President
Hill Dermaceuticals, Inc.
2650 South Mellonville Avenue
Sanford, FL 32773-9361

Re: Docket No. 2004P-0448/CP1

Dear Mr. Roth:

This letter responds to your citizen petition dated September 30, 2004, on behalf of Hill Dermaceuticals, Inc. (Hill), asking the Food and Drug Administration (FDA) not to approve any generic equivalent of Hill's Derma-Smoothe/FS (fluocinolone acetonide .01 percent topical oil) (Derma-Smoothe) unless an applicant submitting an abbreviated new drug application (ANDA) demonstrates that the generic product has the same active ingredient, labeling, and conditions of use as Derma-Smoothe. You also ask that an ANDA applicant demonstrate bioequivalence to Derma-Smoothe by conducting studies with clinical endpoints.

FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0448

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